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30 March 1999

Dockets Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Rm. 1061  
Rockville, MD 20852

Re: Docket No. 98D-0994

Following please find comments to the Draft Guidance for Industry entitled "BACPAC I: Intermediates in Drug Substance Synthesis; Bulk Actives Postapproval Changes: Chemistry, Manufacturing, and Controls Documentation," published in the Federal Register, Volume 63, Number 229, on November 30, 1998.

As requested, specific comments are identified to line number.

#### **Section A. Equivalence of Impurity Profiles**

Line 132. We suggest that for an intermediate, the guidance be revised to "no new impurity is observed at or above 0.1 percent (**or 0.2 percent for an intermediate with only veterinary use**)".

The reason for this is so that the threshold is the same as that for a drug substance for veterinary products, which is described in the guidance for industry on Impurities in New Veterinary Medicinal Products (VICH GL10, 22 October 1998, for consultation at Step 4 - Draft 1).

Thank you for your consideration.

Sincerely,

Carolyn P. Daurio

98D-0994

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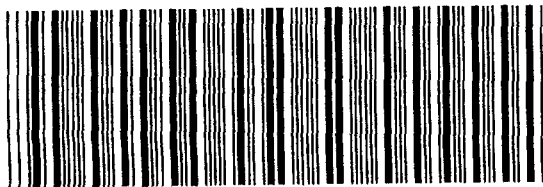
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